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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,918	11/08/2000	Julia J. Dibner	NVI-5009.1	2670

321 7590 06/18/2002

SENNIGER POWERS LEAVITT AND ROEDEL
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16TH FLOOR
ST LOUIS, MO 63102

EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/705,918	Dibner et al
Examiner	**Group Art Unit**
Duffy	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

X Responsive to communication(s) filed on 3-22-02.

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

X Claim(s) 1-54 is/are pending in the application.

Of the above claim(s) 11-24+28-54 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 1-10+25-27 is/are rejected.

Claim(s) _____ is/are objected to.

X Claim(s) 1-54 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

X The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 3,5+6

X Notice of Reference(s) Cited, PTO-892

Notice of Draftsperson's Patent Drawing Review, PTO-948

Interview Summary, PTO-413

Notice of Informal Patent Application, PTO-152

Other _____

Office Action Summary

DETAILED ACTION

1. The response filed 3-22-02 has been entered into the record.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

3. Drawings have been approved by the draftsperson.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Information Disclosure Statement

5. The information disclosure statements filed 2-11-01, 5-11-01 and 8-31-01 have been considered. See attached initialed copies.

Election/Restriction

6. Applicant's election with traverse of Group I, claims 1-10 and 25-27 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search of the claims would require substantially the same search and substantially the same art and as such

administrative economy will be promoted by having all claimed examined in on application. This is not persuasive, the claims do not share the same feature, the different groups of invention are drawn to different compositions. MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups I and II are drawn to distinct inventions which are related as separate products capable of separate manufacture, use or sale as described in the previous Office Action. Restrictions between the inventions is deemed to be proper for the reasons previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups are classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, live sporocysts do not necessarily revel art on treated sporulated oocysts. Clearly different searches and issues are involved in the examination of each Group. Applicants also assert that restriction s not proper when claims include the same distinguishing feature. This is not persuasive, each of the groups use different compositions with different distinguishing features (live sporocyts versus treated sporulated oocyts. As such, the groups do not contain the same feature as

asserted by Applicants. Further, the groups are distinct as claimed for the reasons set forth previously.

The requirement is still deemed proper and is therefore made FINAL.

7. Claims 11-24 and 28-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Rejections - 35 U.S.C. § 112

8. Claims 1-10 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "substantially free" in the claims is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 U.S.C. § 102 or 103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-6, 8-10, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al (WO 96/40233, published 12 December 1999).

Evans et al teach compositions for the in ovo vaccination of domesticated birds using *Eimeria* sporocysts. Evans et al teaches that the sporocysts may be from two or more species of *Eimeria* and include the species of *E. tenella, E. acervulina, E. maxima, E. necatrix, E. mitis, E. praecox* and *E. brunetti* can be used for in ovo vaccination of chicken eggs (page 4, lines 9-12). Evans et al teaches that the sporocysts may be from two or more species of *Eimeria* and include the species of *E. meleagrimitis, E. adenoeides, E. gallopavonis, E. dispersa, E. meleagridis, E. innocua* and *E. subrotunda* can be used for in ovo vaccination of turkey eggs (page 4, lines 15-19). Evans et al teach the sporocysts in suitable liquid carriers such as phosphate-buffered saline. Evans et al teach that the preferred dose is from 10^2 to 10^8 sporocysts per egg (see page 6, lines 25-30). Evans et al teach that contemplates that the preparation may optionally include one or more suspending agents including physiologically suitable gels, gelatins, hydrosols, cellulose or polysaccharide gums. Evans et al teaches that immune stimulants can be used in conjunction with the present vaccination and are preferably administered in the medium containing the dose of *Eimeria* sporocysts (see page 7, lines 9-17). Evans et al teach that the immune stimulants include cytokines, growth factors, chemokines, mitogens and

adjuvants. Evans et al teach all the limitations of the instant claims. With respect to the limitation of "substantially free of extraneous bacterial, fungal and viral contaminants" it is noted that the sporocysts of Evans were prepared by substantially the same method as described in this specification. As such, the composition of live sporocytes described by Evans et al, inherently and necessarily meets this recited property.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same functional characteristics of the claimed composition). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594. It is further noted that the recitation of "for administration by intra yolk sac injection" is deemed an intended use for the composition and does not distinguish the claimed composition of that described by the prior art.

13. Claims 1-10, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) in view of MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991).

Evans et al is set forth *supra*. Evans et al differs by not teaching the addition of preservatives to the vaccine composition.

MacDonald et al teaches vaccines for coccidiosis comprising live sporulated oocysts from different strains of *Eimeria* species and their use alone or in combination (column 5, last paragraph). MacDonald et al teach that there is little cross-species protection for different Eimeria species (column 2, lines 53-62). MacDonald et al teaches that the vaccines will comprise a suspension of the oocysts in "sterile distilled water" containing a

suspending agent. MacDonald et al also teach that a preservative may be present to inhibit contamination with other organisms, e.g. formalin at a concentration of, for example 0.001% w/w (see column 7, lines 32-47).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add a preservative according to MacDonald et al to the in ovo vaccine composition of Evans et al because MacDonald et al teach that it is desirable to add preservatives to vaccines to inhibit contamination with other organisms.

14. Claims 1-10 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) in view of MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991) as applied to claims 1-10, 25 and 27 and further in view of Rolinski et al (Medycyna Weterynaryjna, 44(8):abstract 1988) or Thaxton (U.S. Patent 5,311,841; issued may 17, 1994).

Evans et al and MacDonald as combined is set forth *supra*. The combination differs by not teaching the addition of gentamicin as a preservative. It is noted that gentamicin is set forth in the specification at page 24, first full paragraph as a preservative, it is also an well known bactericidal antibiotic effective for treatment of bacterial diseases.

Rolinski et al teaches that gentamicin inhibits common Salmonella strains isolated from animal and poultry at a minimum inhibitory concentration at 0.25-5.0 ug/ml.

Thaxton teaches a method for the delivery of medicaments to newly hatched poultry via intra-yolk sac injection. Thaxton teaches that the method of the invention provides a particular advantage in the treatment of coccidiosis in poultry and the method provides an effective vaccine for the treatment of coccidiosis. Thaxton teaches immunization of newly hatched chicks by means of intra-yolk sac injection (column 16, see Example 4) of sporulated oocysts for coccidiosis. Thaxton et al teach that the results

indicate that intra-yolk sac injection and trickle treatment of sporulated oocysts provided useful protection to the chicks (see columns 19-20, bridging paragraph). Thaxton et al teach that the method and device is useful to deliver vaccines, antibiotics such as gentamicin and probiotics (see column 4, lines 30-68). Thaxton et al teach that gentamicin is used to prevent or retard early bacterial infection, to promote early growth, and reduce post-hatching stress.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the composition of Evans et al and MacDonald as combined *supra* by the addition of the minimal inhibitory concentration of the antibiotic gentamicin as set forth by Rolinski et al because because MacDonald et al teach that it is desirable to add preservatives to vaccines to inhibit contamination with other organisms and Rolinski et al teach gentamicin inhibits common poultry bacteria at a concentration at 0.25-5.0 ug/ml. One would be motivated to formulate the antibiotics in combination with the vaccine because such a formulation would provide the expected benefits of preservation of the vaccine product and protection from infection.

Alternatively, it would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the composition of Evans et al and MacDonald as combined *supra* by the addition of the antibiotic gentamicin at any suitable concentration when used for intra-yolk sack injection because Thaxton teaches that the device can also administer antibiotics that are useful to prevent or retard early bacterial infection, to promote early growth, and reduce post-hatching stress and one would be motivated to formulate the antibiotics in combination with the vaccine because such a formulation would provide the expected benefits of retarding bacterial growth that may occur, vaccination for coccidiosis and certainly reduce trauma to the chicks by

reducing the number of injections and the formulation of the optimal for the expected benefits is well within the skill of the art.

Pertinent Prior Art

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jenkins et al (Reference 11 on PTOL-1449 of 2-8-01) is cited to teach that "treatment with sodium hypochlorite removes contaminating bacteria (see page 75, column 1, Materials and Methods).

Status of Claims

16. No claims are allowed.

17. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
June 16, 2002

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600